

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: December 19, 2008
Electronic Signature for Megan E. Williams: /Megan E. Williams/

Docket No.: BGG-A117CNRCE2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Michele Sanicola-Nadel *et al.*

Application No.: 10/693,538

Confirmation No.: 4018

Filed: October 23, 2003

Art Unit: 1643

For: CRIPTO BLOCKING ANTIBODIES AND
USES THEREOF

Examiner: Huff, Sheela J.

MS Patent Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 CFR § 1.702(b)(2)

Dear Sir:

1. This statement is respectfully submitted in support of the "Application for Patent Term Adjustment Including Request for Reconsideration Under 37 CFR §1.705(b)" for the above-referenced application. In view of the following, it is respectfully requested that Applicants be granted a patent term adjustment of **508 days** for the above-referenced application.

2. The patent term adjustment on the Determination of Patent Term Adjustment Under 35 U.S.C. §154(b) ("Determination") that was attached to the Notice of Allowance is 128 days (a copy of the Determination is submitted herewith as Exhibit A). A copy of the PTO's Patent Term Adjustment calculation ("PTA Sheet") available on Private Pair is also submitted herewith as Exhibit B. Applicants respectfully submit that the determination of 128 days of patent term adjustment is incorrect for the reasons discussed below.

3. The factual bases for the above adjustment are set forth as follows:

A. Examination Delays Pursuant to 37 CFR §1.702 and §1.703

Pursuant to 37 CFR §1.703(f), the period of adjustment of the term of the patent under §1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704 (the period of Applicant Delay). In the above-referenced application, Applicants are entitled to a period of examination delay equal to the sum of the periods of delay under §1.703(a) and (b) for the reasons set forth below.

(i) “14 Month Delay” Pursuant to §1.703(a)(1)

In accordance 37 CFR §1.703(a)(1), Applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months after the actual filing date (*i.e.*, by December 23, 2004). As shown in the PTO's Patent Term Adjustment calculation (Exhibit B), the Office failed to mail an action under 35 U.S.C. §132 (a Restriction Requirement) until October 18, 2005. As such, Applicants are entitled to a period of patent term adjustment beginning December 24, 2004 and ending on October 18, 2005, the date of mailing of the Restriction Requirement by the Office. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is **299 days**. This is consistent with the PTA Sheet (Exhibit B) from the Office.

(ii) “Three Years Delay” Pursuant to 37 CFR §1.703(b)

It is anticipated that the Office will not comply with the requirement of 35 U.S.C. §154(b) and 37 CFR §1.702(b), which requires issuance of a patent within 3 years after the date on which the application was filed under 35 U.S.C. §111(a). As indicated in the Notice of Allowance, a patent is projected to issue on June 9, 2009. As such, there is an anticipated delay of 960 days.

However, since the exclusionary period for continued examination set forth in 37 CFR §1.702(b)(1) applies to the instant patent, the number of days in the period beginning on the date on which Patentees first filed a Request for Continued Examination (November 8, 2007) and ending on the future issue date of a corresponding patent (June 9, 2009), *i.e.*, 580 days, is excluded from the period of Three Years Delay (*i.e.*, 960 days). Therefore, in accordance with 37 CFR §1.703, Patentees have calculated a maximum period of Three Years Delay based on the period of time beginning on the day after the date that is three years after the date on which the

above-referenced patent was filed under 35 U.S.C. § 111(a) (*i.e.*, October 24, 2006), and ending on the date Patentees first filed a Request for Continued Examination (*i.e.*, November 8, 2007). This period of delay is **380 days**.

(iii) Calculation of Total Period of Examination Delay Pursuant to 37 CFR §1.703(f)

As set forth in 37 CFR §1.703(f), the period of examination delay based on the grounds set forth in 37 CFR §1.702 is the sum of the period of 14 Month Delay (299 days) and the minimum period of Three Years Delay (380 days), to the extent these periods of delay are not overlapping. As the period of 14 Month Delay ended on October 18, 2005, prior to the first day of the period of Three Years Delay, *i.e.*, October 24, 2006, Applicants submit that these periods are not overlapping. Accordingly, the sum of the total examination delays results in a total examination delay of **679 days**.

B. “Applicant Delay” Pursuant to 37 CFR §1.704

Pursuant to 37 CFR §1.704 the period of adjustment of the term of the patent due to examination delay is reduced by the period of Applicant Delay. As shown in the PTO’s Patent Term Adjustment calculation (Exhibit B), the Office has calculated a period of Applicant Delay of 171 days.

(i) Applicant Delay for Filing an Information Disclosure Statement

Applicants respectfully submit that a period of Applicant Delay of **19 days** accrued for the delayed submission of an Information Disclosure Statement (IDS) on February 6, 2006. This IDS was filed without a statement under 37 CFR §1.704(d), 19 days after the filing of a response by Applicants to the Restriction Requirement on January 18, 2006. This period is consistent with the PTA Sheet (Exhibit B) from the Office. Pursuant to 37 CFR §1.704(c)(8), this 19 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(ii) Applicant Delay for Responding to Non-Final Action Dated March 16, 2006

Applicants respectfully submit that an additional period of Applicant Delay of **61 days** accrued for the delayed submission of an Amendment and Response on August 16, 2006. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR

§1.704(b), this 61 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(iii) Applicant Delay for Responding to Non-Final Action Dated November 1, 2006

Applicants respectfully submit that an additional period of Applicant Delay of **89 days** accrued for the delayed filing of a Response to Non-Final Action on May 1, 2007. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 89 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(iv) Applicant Delay for Responding to Notice of Allowance Dated February 25, 2008

Applicants respectfully submit that an additional period of Applicant Delay of **2 days** accrued for the delayed filing of a Request for Continued Examination and Information Disclosure Statement on May 27, 2008. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 2 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(iv) Calculation of the Total Period of Applicant Delay

In view of the above, Applicants have calculated a total period of Applicant Delay of **171 days** which is the sum of the following Applicant Delays: (i) the 19 day period ; (ii) the 61 day period; (iii) the 89 day period ; and (iv) the 2 day period. Applicants respectfully submit that the period of Applicant Delay is **171 days**. This is consistent with the PTA Sheet (Exhibit B) from the Office.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR

§1.702(f)

As set forth in 37 CFR §1.703(f), Applicants are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Applicant Delay. Therefore, Applicants submit that the correct patent term adjustment for the above-referenced application is **508 days**, which is the difference between the total period of examination delay (679 days) and the period of Applicant Delay (171 days).

In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment of **508 days** for the above-referenced application.

Dated: December 19, 2008

Respectfully submitted,

By /Megan E. Williams/
Megan E. Williams
Registration No.: 43,270
LAHIVE & COCKFIELD, LLP
28 State Street
Boston, Massachusetts 02109
(617) 227-7400
(617) 742-4214 (Fax)
Attorney For Applicant